II. Safety and Effectiveness Summary

A. *Contact Information*

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Micrus Corporation
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B. *Device Name*

Micrus MicroCoil Delivery System, MDS03

Device, Artificial Embolization

Regulation Number: 882.5950

Product Code: HCG

Device Class: III

C. *Predicate Device(s)*

Number	Description	Clearance Date
K951256	Detachable Platinum Coil (Guglielmi Detachable Coil)	9/8/95
K960705	Guglielmi Detachable Coil	5/21/96
K971395	Guglielmi Detachable Coil (GDC), Fibered Platinum	7/14/97
K991139	Guglielmi Detachable Coil (GDC)	12/22/99
K993417	GDC-10 and GDC-18 Guglielmi Detachable Coil (3D Shape GDC)	1/21/00

D. Device Description

The MMDS consists of three components:

- The "MicroCoil System" (MMCS), which consists of the platinum embolic coil ("MicroCoil") attached to a Device Positioning Unit (DPU) (single use, sterile),
- The Detachment Control Box (DCB) (reusable, non-sterile), and
- The Connecting Cable (single use, sterile)

Each of the system components is sold separately.

The Micrus MicroCoils are available in Spherically shaped configurations as well as Helically shaped configurations of various diameters/dimensions. The coils are fabricated from a platinum alloy wire, which is first wound into a primary coil, and then formed into a secondary (spherical or helical) shape.

The MicroCoils are provided attached to a Device Positioning Unit (DPU). The DPU is designed with variable stiffness: It is most stiff at the proximal end for pushability, transitions to increased flexibility in the mid-section, and becomes most flexible at the distal end for successfully navigating the tortuosity of the cerebral vasculature. The DPU is fabricated from various materials including stainless steel, nitinol, platinum and polymer sheathing. It contains 2 copper conductor wires down the center, which carry the electrical energy to a platinum resistive heating coil on the distal tip of the device. The DPU is self grounded, requiring no external grounding through the patient, a grounding pad, etc.

The MicroCoil is detached from the DPU through the heat initiated shearing of a highly oriented, high tensile strength polyethylene (PE) fiber upon the clinician's command, once the coil is deployed into the aneurysm as desired. The DPU is then removed from the microcatheter and discarded.

The Detachment Control Box (DCB) is a self-contained, battery operated device which provides the controlled electrical energy for detachment of the MicroCoil from the DPU. During the procedure it remains outside of the sterile field as is the case with the predicate system. It has no user adjustments for output voltage, output current or detachment cycle time. It has an on/off button, and a detach cycle start button, as well as voltage and current displays and fault and low battery indicators. When the clinician depresses the detach button, the DCB outputs a constant voltage of 6.5 VDC at a nominal current of 125mA for 10 seconds. The delivered electrical energy serves to heat a platinum resistive heating coil at the distal end of the DPU, thereby initiating a heat shearing of the PE fiber which holds the MicroCoil to the DPU. Once the fiber shears, the MicroCoil is free from the DPU ("detached"), and the DPU is withdrawn and discarded.

The Connecting Cable (CCB) is used to connect the MicroCoil System to the Detachment Control Box. It utilizes proprietary connectors to prevent accidental or inappropriate connections to other devices. It traverses from the MMCS, which is within the sterile field, to the DCB which is outside the sterile field. It is provided sterile, and discarded after a single patient treatment.

E. *Intended Use*

The Micrus MicroCoil Delivery System (MMDS) is intended for endovascular embolization of intracranial aneurysms that – because of their morphology, their location or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques or b) inoperable.

F. *Intended Use Predicate Device*

"The Guglielmi Detachable Coil is intended for embolization of those intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) inoperable. The GDC is also intended for embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae."

G. *Technological Comparison*

Characteristic	Micrus	GDC
MicroCoil System		
How supplied	Sterile, single use. MicroCoil attached to the DPU, polyethylene introducer over MicroCoil, in plastic packaging hoop.	Sterile, single use. Embolic coil attached to the pusher wire, polyethylene introducer over embolic coil, in plastic packaging hoop.
Implantable Embolic Coil		
Materials of construction	Platinum/Tungsten alloy wire & Au/Sn solder.	Platinum/Tungsten alloy wire, stainless steel & Au/Sn solder.
Shape	3D Spherical and Helical with atraumatic tip.	3D Shape and Helical with atraumatic tip.
Dimensions	Various diameters and lengths to treat a variety of aneurysm sizes.	Various diameters and lengths to treat a variety of aneurysm sizes.
Radiopacity	Radiopaque from Pt alloy wire.	Radiopaque from Pt alloy wire.
MRI Compatibility	Yes	Yes
Method of attachment to device positioning unit	High tensile strength, highly oriented polyethylene fiber.	Welded or soldered to wire.
Method of detachment from device positioning unit	Shear PE fiber with a loop of a resistively heated coil.	Electrolytic corrosion of positioning wire near junction of implantable coil.
Provided:	Sterile, single use	Sterile, single use
Device Positioning Unit		
Physical	Variable stiffness composite introducer (most flexible distally, medium flexibility in mid-section and stiffest proximally) to allow pushing of the embolic coil through the tortuous cerebral vasculature.	Variable stiffness guidewire (most flexible distally, medium flexibility in mid-section and stiffest proximally) to allow pushing of the embolic coil through the tortuous cerebral vasculature.
Construction	Stainless steel hypotube (proximal), stainless steel braid (mid) and polymer (distal) sheathing for 2 conduction wires and distal RH coil.	Variably ground stainless steel wire, with polymer coverings in the distal section to facilitate electrochemical corrosion of wire to release coil.
Working Length	175 cm	175 cm
Package Configuration	In plastic packaging hoop, with introducer in place (for introduction of MicroCoil into the microcatheter)	In plastic packaging hoop, with introducer in place (for introduction of coil into the microcatheter)
Compatible with:	Microcatheters with minimum 0.14" i.d. ("10" sized systems) or 0.16" i.d. ("18" sized systems) with 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14)	Microcatheters with minimum 0.14" i.d. ("10" sized systems) or 0.16" i.d. ("18" sized systems) with 2 radiopaque tip markers 3 cm apart (examples: Tracker 10, Tracker 18, Excel 14, Prowler 10, Prowler 14)

Characteristic	Micrus	GDC
Connecting Cables		
How supplied	Sterile, single use	Sterile, single use
Physical	Single cable with proprietary connectors to fit only the Micrus DCB and the Micrus MicroCoil System	Two separate cables with proprietary connectors at one end to fit the GDC Poser Supply, "Test Lead Clip" type connector to grasp pusher wire and patient grounding electrode
Length	262 cm.	152 and 274 cm.
Detachment Box		
How supplied	Non-Sterile, reusable. Used outside the sterile field.	Non-Sterile, reusable. Used outside the sterile field.
Power Source	Alkaline batteries.	Alkaline batteries.
Displays	Voltage, Current, Low Battery, Fault, Detach Cycle	Voltage, Current, Low Battery, Fault (Check), Detach, Time
Detachment Cycle Duration	10 seconds	Variable (could be more than 60 minutes)
Output Voltage	6.5 VDC	Variable (up to 7.4 VDC) to achieve 1 mA current through device and patient ground
Output Current	125 mA nominal, 200 mA max.	Variable: Attempts to achieve 1 mA through device and patient ground.
"Detach" feedback	"Detach Cycle" light goes from illuminated to off. Clinician verifies detachment fluoroscopically per device labeling.	Tone sounds and "Detach" light goes on. Based upon voltages seen during detachment cycle, clinician may re-initiate detachment cycle, or verifies detachment fluoroscopically per device labeling.
Method of attaching Connecting Cable to Detachment Box	Proprietary connector, fits only one way to assure proper polarity.	Banana plugs, one male, one female to assure proper polarity.
Flow of Current	From positive terminal, through positive lead in connecting cable, through positive conductor of DPU, through resistance heating coil, through negative conductor of DPU, through negative lead in connecting cable, back to negative terminal of detachment control box.	From positive terminal, through positive connecting cable lead, through stainless steel pusher wire, through patient's circulatory system to needle placed in patient's blood vessel or a grounding pad, through negative connecting cable lead, back to negative terminal of GDC Power Supply box.
Accessory Products Required to Perform the Procedure. * - Not provided as part of the system, chosen based upon physician experience and preference.	Micrus Sterile Connecting Cable Micrus Detachment Control Box 5-7F Guide Catheter* Microcatheter (see above)* Guidewire compatible with microcath* Continuous saline/hep saline flush* Rotating hemostatic valves* 3-Way stopcock* 1-Way valve* IV pole* Femoral Sheath* Alkaline Batteries*	Sterile Connecting Cables for GDC GDC Power Supply 5-7F Guide Catheter* Microcatheter (see above)* Guidewire compatible with microcath* Continuous saline/hep saline flush* Rotating hemostatic valves* 3-Way stopcock* 1-Way valve* IV pole* Femoral Sheath* Alkaline Batteries*

This technological comparison demonstrates the substantially equivalent technologies used in the Micrus MicroCoil Delivery System as compared with the predicate Boston Scientific/Target Therapeutics GDC System.

H. *Discussion of Non-Clinical Tests and Conclusions*

The non-clinical tests performed on the Micrus MicroCoil System were based upon the intended use of the device, the performance of the predicate device GDC system, and an analysis of the failures of the predicate device (as based upon a review of applicable MDR reports).

The following table outlines the important device characteristics and the non-clinical test data generated:

Test or Comparison	**MicroCoil Delivery System, MDS03**
Friction in the Microcatheter	Substantially equivalent to or slightly less as compared with predicate device.
Tensile Strength, Coil to DPU Junction	Coil becomes destroyed before junction fails. Not susceptible to detachment from manipulation. Substantially equivalent to predicate GDC device.
Premature Detachment/Autodetach	No premature detachment/autodetach caused by exposure to blood, body fluids, body temperatures or repeated manipulation.
Time & Reliability of Detachment	10 second detachment cycle, greater than 95% first fire detachment reliability. Greater than 99% detachment reliability.
Reliability after Fatigue	Ability to withstand fatigue while maintaining electrical/physical/functional integrity demonstrated.
Particulate Generation on Detachment	No generation of potentially embolic particulates on detachment.
Thermocoagulation on Detachment	No thermocoagulation from heating during detachment.
Heating Effect on Tissue on Detachment	No adverse histologic impact to surrounding tissues from heating during detachment.
Radiopacity	Applicable aspects of the system equivalent in radiopacity to predicate device.
Coil Stiffness/Softness	Substantially equivalent to predicate device.
Aneurysm Packing Ability	Ability to pack aneurysms to point of no further inflow of blood demonstrated.
Coil Positional Stability/Aneurysm Occlusion	Positional stability and aneurysm occlusion maintained through at least 6 months of implant.
Biocompatibility of Materials	Materials of implant/contact validated per ISO 10993-1.
System Performance Validation	Meets requirements of Design Specification for user interface, functionality and performance.
Battery Life Testing	Meets Design Specification requirements.
Transit Testing	Meets requirement of the test.
Packaging Validation	Prevention of microbial recontamination for at least 3 years.
Sterilization Validation	Minimum Sterility Assurance Level of 10^{-6}.
Electrical Safety Testing	Passes requirements of EN-60601-1.
MRI Compatibility of Implant	Meets MRI compatibility guidelines.

This non-clinical testing has demonstrated the substantially equivalent performance of the Micrus MicroCoil Delivery System with the predicate Boston Scientific/Target Therapeutics GDC System.

I. Summary of Safety and Effectiveness

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Micrus Corporation, it is concluded that the MicroCoil Delivery System is substantially equivalent to the Boston Scientific/Target Therapeutics GDC System in safety and effectiveness.

Tom Holdych

Vice President, RA/CA/QA

Micrus Corporation

July 5, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2001

Mr. Tom Holdych
Vice President, Regulatory Affairs,
Clinical Affairs and Quality Assurance
Micrus Corporation
495 Clyde Avenue
Mountain View, California 94043

Re: K002056
Trade Name: Micrus MicroCoil Delivery System
Regulatory Class: III
Product Code: HCG
Dated: July 5, 2000
Received: July 6, 2000

Dear Mr. Holdych:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: 510(k) Number (if known):

Indications for Use:

The Micrus MicroCoil Delivery System (MMDS) is intended for endovascular embolization of intracranial aneurysms that – because of their morphology, their location or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques or b) inoperable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: ✓
(Per 21 CFR 801.109)

Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002056